

REMARKS

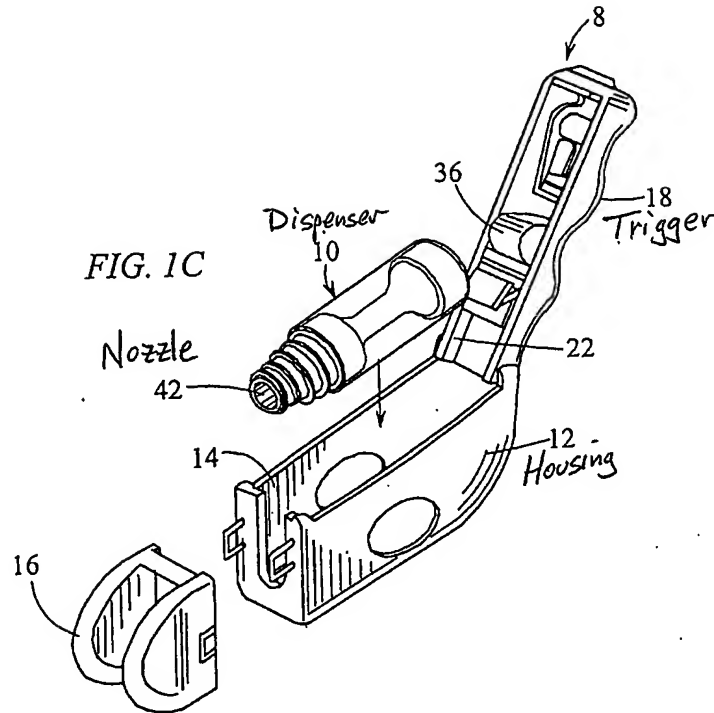
In response to an Office Action mailed on April 21, 2006, Applicant respectfully requests that the Application be reconsidered in view of the following Remarks. Twenty-one claims are presented for examination. Of these, claims 1, 10 and 16 are independent, and the remaining claim(s) is(are) dependent.

The Examiner rejected claims 1-21 under 35 U.S.C. 102(a) as being anticipated by U.S. Pat. No. 6,761,286 to Py, *et al.* ("Py"). The Applicant respectfully traverses this rejection.

The Application discloses and claims a medical valve to permit fluid flow between a proximal port and a distal port. Such a valve can, for example, be secured to a patient to provide a sealed port that may repeatedly be accessed to non-invasively inject fluid into, or withdraw fluid from, a patient's vasculature, without repeatedly piercing the patient's skin with a needle. Typically, a nozzle or syringe is inserted into the proximal port of the valve to inject or withdraw the fluid.

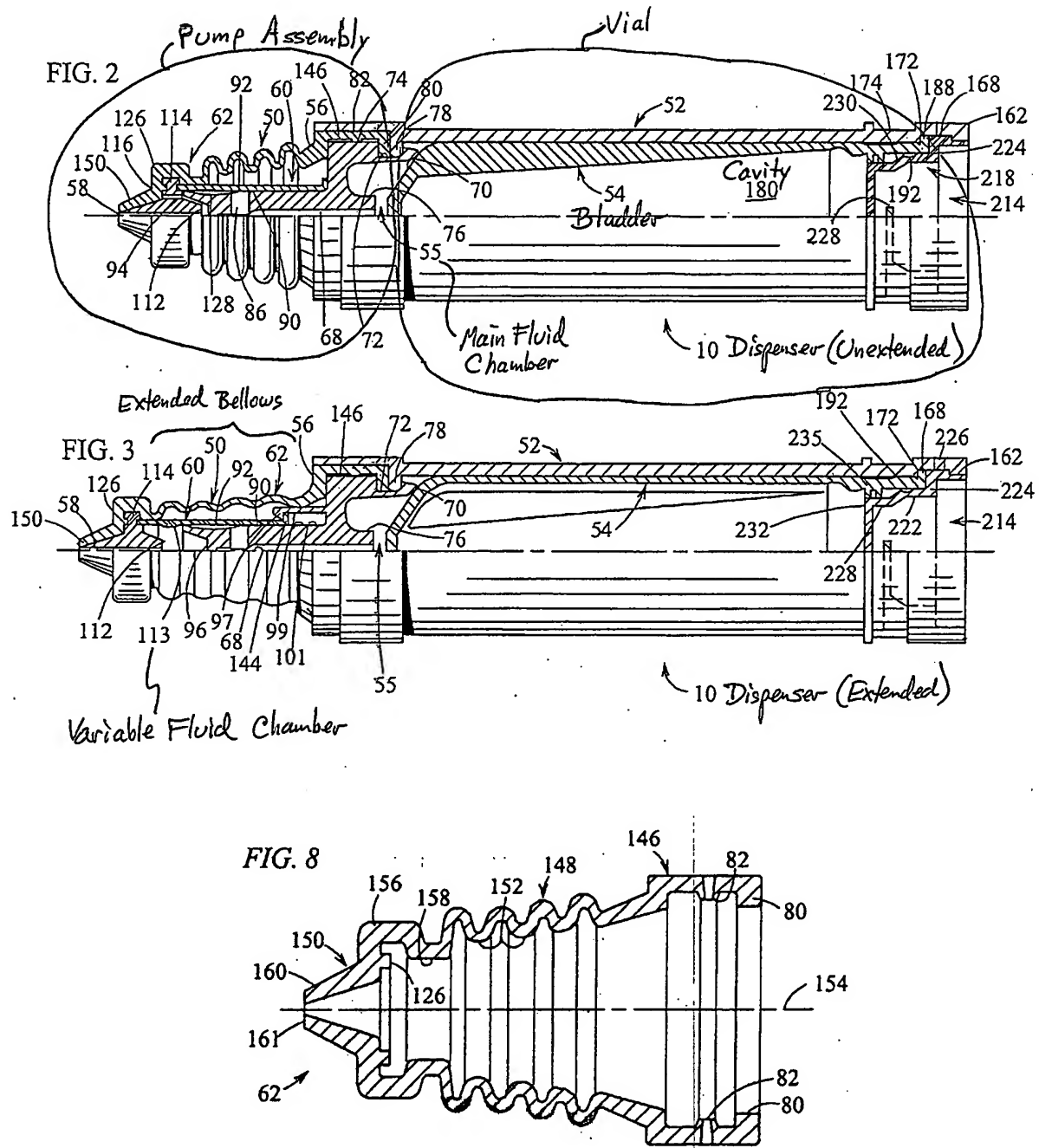
As discussed in the Application, the disclosed and claimed valve substantially eliminates fluid drawback when the nozzle or syringe is withdrawn from the valve, thereby solving a problem associated with prior-art medical valves. The undesired drawback is substantially eliminated due, at least in part, to operation of a fluid chamber in the disclosed and claimed medical valve. The fluid chamber forces fluid out of the valve, via the distal port (i.e., toward the patient), as the valve is being closed, before the nozzle or syringe is withdrawn from the proximal port. Accordingly, fluid should not be drawn into the valve when the nozzle or syringe is withdrawn.

On the other hand, Py discloses an apparatus 8 (Fig. 1C) for dispensing a predetermined dose of medicament into an eye of a patient. (For the Examiner's convenience, copies of referenced figures, some with annotations, are included herein.) The apparatus 8 includes a hand-held, trigger-operated housing 12 and a pre-filled dispenser 10 that can be loaded into the housing 12. The dispenser 10 stores several doses of the medicament. When the patient places the apparatus 8 adjacent the eye and squeezes a trigger 18, the dispenser 10 meters out the predetermined dose. A nozzle 42 (labeled nozzle 58 in Fig. 2 and other drawings) on the dispenser 10 releases the medicament into the ocular cul-de-sac of the patient's eye. (Py: col. 7, line 63 to col. 8, line 17.)



The dispenser 10 includes an extendable pump assembly 50 (Fig. 2) and a rigid vial 52. The pump assembly 50 includes a resilient bellows 148 (Fig. 8). The vial 52 contains the medicament.

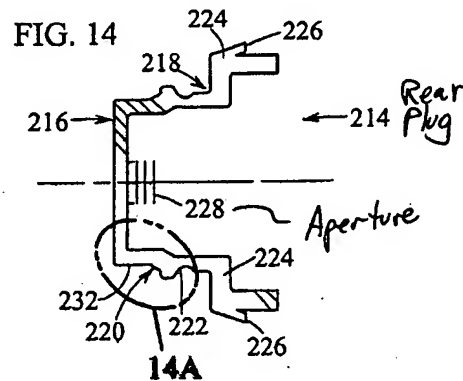
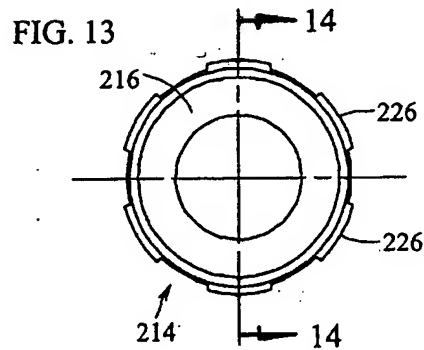
When the trigger 18 is operated, the apparatus 8 extends (i.e., pulls on to lengthen) the dispenser 10. (Col. 7, line 65 to col. 8, line 17.) The vial 52 is rigid, so the bellows of the pump assembly 50 extends (i.e., the pump assembly 50 becomes longer). An unextended dispenser 10 is shown in Fig. 2, and an extended dispenser 10 is shown in Fig. 3 (Col. 5, lines 60-67.) As the resilient bellows 148 extends, the predetermined dose of medicament is drawn from a main fluid chamber 55 into a variable volume fluid chamber 113. Py refers to this action as “priming the pump.” (Col. 11, lines 40-52.) As the trigger 18 is further operated, the apparatus releases the extended dispenser 10. The resiliency of the bellows 148 causes the pump assembly 50 to contract and release the dose through the nozzle 42, into the eye. (Col. 8, lines 39-57.)

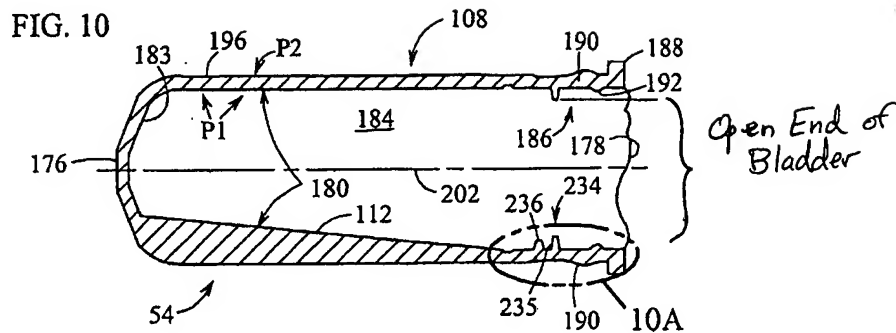


As shown in Fig. 2, the dispenser 10 also includes a flexible bladder 54, which separates the vial 52 into two portions. The left portion (referred to as the fluid chamber 55) contains the medicament. The right portion (referred to as a cavity 180) contains air. Initially, i.e., when the fluid chamber 55 is full of medicament, the cavity 180 contains little air. Then, each time the

pump is primed, more air enters the cavity 180 to compensate for the volume of medicament that is withdrawn from the main fluid chamber 55. (Col. 13, line 63 to col. 14, line 10.)

The dispenser 10 also includes a rear plug 214 (Figs. 13 and 14) that mates with an open end 178 (Fig. 10) of the bladder 54. The rear plug 214 includes an aperture 228 in a side wall 218 (Fig. 2)) as needed to make up for volume lost from the main fluid chamber 55 as the pump is primed. (Col. 16, lines 51-55; col. 16, line 67 to col. 17, line 3; col. 17, lines 25-37; and col. 17, line 54 to col. 18, line 5.)





No fluid (medicament, air or other fluid) flows between the aperture 228 and the nozzle 58. (Col. 18, lines 8-14.)

The Examiner asserted that the nozzle 58, the rear plug 214 and various other portions of the dispenser 10 anticipate elements recited in the claims. The Applicant respectfully disagrees with several of these assertions. Several claim elements are discussed below and distinguished from the cited art.

Fluid Channel, Ports

Claim 1 recites, “a body forming an interior, a proximal port, and a distal port, the interior having a fluid channel between the proximal port and the distal port.” (Emphasis added.) The Examiner cited Py’s nozzle 58 as corresponding to the recited proximal port and Py’s rear plug 214 as corresponding to the recited distal port. However, as discussed above, no fluid flows between Py’s nozzle 58 and rear plug 214. Thus, Py does not disclose a body that has a fluid channel between a proximal port and a distal port, as recited in claim 1. Similarly, Py does not disclose ports with a fluid channel therebetween, as recited in claim 1.

Valving Element

Claim 1 recites “a valving element within the interior of the body, the valving element controlling fluid flow between the proximal and distal ports.” (Emphasis added.) Because there can be no fluid flow between Py’s nozzle 58 and Py’s rear plug 214, Py does not disclose a valving element that controls a fluid flow between a proximal and a distal port, as recited in claim 1.

Resilient Member

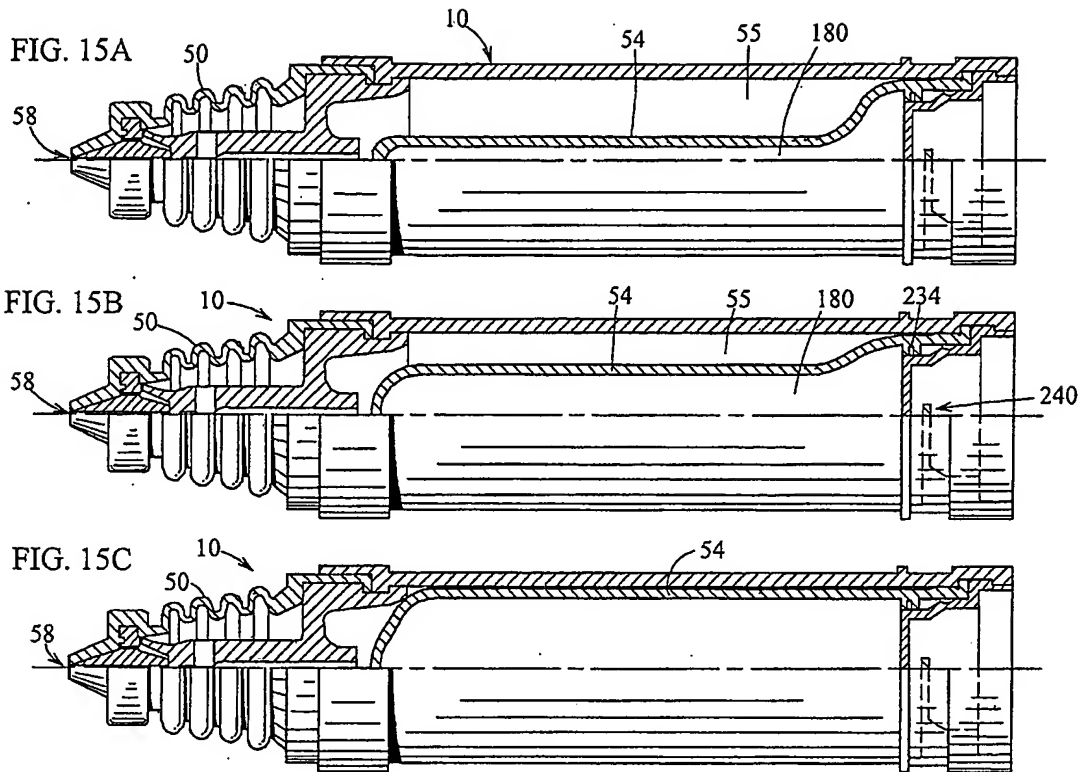
Claim 1 recites, “the valving element including a resilient member and a plug, the resilient member forming a fluid chamber..., the fluid chamber being at least part of the fluid channel.” (Emphasis added.) The Examiner, citing Py (col. 3, lines 18-60), appears to analogize Py’s flexible bladder 54 with the recited resilient member. However, according to claim 1, the resilient member forms a fluid chamber that is at least a part of the fluid channel. As discussed above, Py does not disclose a fluid channel between a proximal port and a distal port. Therefore, Py’s bladder 54 cannot form anything that is at least part of such a fluid channel. Thus, Py does not disclose a resilient member, as recited by claim 1.

Valving Element

The Examiner cited Py’s one-way valve (col. 8, line 50) as anticipating the recited valving element. The one-way valve is opened by pressure of the medicament, when the bellows 148 contracts. (Figs. 2 and 6; col. 11, lines 16-39.) The cited one-way valve is located at the tip of the nozzle 58. As noted above, Py discloses no valving element that controls fluid flow between the proximal and the distal ports. Py’s one-way valve does not control fluid flow between the nozzle 58 (which the Examiner analogized to the recited proximal port) and the rear plug 214 (which the Examiner analogized to the recited distal port), as recited in claim 1. Neither the one-way valve nor any other part of Py’s disclosure meets the valving element requirement of claim 1.

Plug, Radial Expansion

Claim 1 recites, “...a plug, ...the plug, radially expanding the resilient member when the valve transitions from the closed mode to the open mode.” (Emphasis Added). Even if, *arguendo*, Py does disclose a valving element, Py does not disclose a plug or any other structure that radially expands a resilient member when the valve transitions from the closed mode to the open mode. If anything, Py’s structures operate opposite to the claim recitations. According to Py’s disclosure, while the dispenser 10 is being extended, medicament is drawn from the main fluid chamber 55 into the variable volume fluid chamber 113. As the medicament is drawn from the fluid chamber 55, air is drawn into the bladder 54 to make up for the decreased volume of medicament in the main fluid chamber 55. Figs. 15A, 15B and 15C show the dispenser 10 in full, half-full and empty conditions, respectively. (Col. 6, lines 50-54.)



However, while the pump is being primed, the one-way valve is closed. Thus, the bladder 54 (which the Examiner appears to analogize to the recited resilient member of the valving element) expands while the one-way valve is closed. By the time the medicament begins to be dispensed, i.e., when the one-way valve transitions from a closed mode to an open mode, the cavity 180 defined by the bladder 54 has already been filled with air. Thus, when the one-way valve transitions from the closed to the open mode, the bladder 54 is not expanded, as required by claim 1.

Furthermore, the cited plug 214 does not expand the bladder. Instead, air drawn into the cavity 180 expands the bladder 54. Thus, Py does not disclose a plug that radially expands the resilient member when the valve transitions from a closed mode to an open mode, as recited in claim 1.

Conclusion

Py does not disclose any of the claim elements or limitations discussed above. Thus, Py does not anticipate the invention recited in claim 1. Furthermore, no art of record, either alone or

in combination, discloses or suggests a medical valve that includes a body, proximal and distal ports, fluid channel, valving element, resilient member and plug, as recited in claim 1. For at least the reasons given above, claim 1 is believed to be allowable.

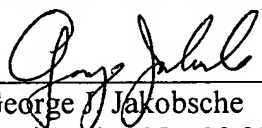
Independent claims 10 and 16 each contains at least some of the recitations discussed above, with respect to claim 1. Each of these claims is, therefore, believed to be allowable, for at least the reasons given above, with respect to the corresponding recitations.

Claims 2-9, 11-15 and 17-21 depend directly or indirectly from claim 1, 10 or 16. These dependent claims are, therefore, believed to be allowable, for at least the reasons discussed above, with respect to claim 1, 10 and/or 16.

For all the foregoing reasons, it is respectfully submitted that the present application is in a condition for allowance, and such action is earnestly solicited. The Applicant hereby requests that any extension-of-time or other fee required for timely consideration of this application, but that is not submitted herewith, be charged to Deposit Account No. 19-4972. The Examiner is encouraged to telephone the undersigned attorney to discuss any matter that would expedite allowance of the present Application.

In addition, the Applicant respectfully requests a telephonic examiner interview between the undersigned attorney and the Examiner. After the Examiner has reviewed this Amendment, but before the Examiner issues a subsequent Office Action, the Applicant respectfully requests the Examiner to contact the undersigned attorney to schedule such an interview.

Respectfully submitted,


George J. Jakobsche
Registration No. 39,236
Attorney for Applicant

BROMBERG & SUNSTEIN LLP
125 Summer Street
Boston, MA 02110-1618
617-443-9292 (tel)
617-443-0004 (fax)

01600/00162 514274.1